MEMORANDUM

DATE: 29-April-2003

SUBJECT: Benfluralin: Health Effects Division (HED) Metabolism Assessment

Review Committee (MARC) Decision Document.

Chemical: 084302

Case: 2030

FROM: Richard Griffin, Risk Assessor

and

David Anderson, Toxicologist Reregistration Branch II Health Effects Division

THROUGH: Christine Olinger, HED MARC Chair

and

Alan Nielsen, Branch Senior Scientist RRBII/HED

TO: Yan Donovan, HED MARC Executive Secretary (7509C)

Introduction

The HED Metabolism Assessment Review Committee (MARC) met on 19-March-2003 to discuss benfluralin residues of concern in plants, livestock, and drinking water.

Material Reviewed

The MARC reviewed a briefing document (dated 3/12/03) prepared by R. Griffin and D. Anderson (HED), with data concerning drinking water provided by W. Eckel (EFED).

MARC Members in Attendance Abdallah Khasawinah, Alberto Protzel, Rick Loranger,

Christine Olinger, Yan Donovan, Leung Cheng, Bill Wassell, Norman Birchfield, PV Shah, John Doherty.

Members in Absentia Sheila Piper, Leonard Keifer, Steve Knizner.

Alternate Members attended David Soderberg, George Kramer.

Non Members Diane Isbell, Richard Griffin, William Eckel, David Anderson.

MARC Decision Table

The MARC recommendation for the benfluralin metabolites/degradates to be included in dietary and aggregate risk assessment, and the metabolites to be included in tolerance expression are summarized below.

Chemical: Benfluralin		
Meeting Date: 19-March-2003		
Residues of Concern		
Matrix	For Risk Assessment	For Tolerance Expression
Plants	Parent benfluralin	Parent benfluralin
Rotational crops	No decision	No decision
Livestock	Not required (Category 3)	Not required (Category 3)
Drinking Water	Parent plus degradates: LY- 48800(B35), LY-67255, LY- 50030, LY-274766, LY-65138, LY-51783 (B34), and B12	N/A

Rationale

Plants (primary crop): The MARC reaffirmed that benfluralin per se is the residue of concern for tolerance expression and for dietary risk assessment. Agency reviewed metabolism studies on alfalfa, lettuce and peanut indicate that benfluralin per se was found at very low levels. Up to half of the radioactivity was incorporated into natural components (lignin, cellulose, and proteins), while the remaining aqueous- and ethyl acetate-extractable residues contained many components of varying polarities. No single component constituted a significant percentage (>10%) of the total radioactive residue (TRR). The MARC concludes that, based on the structures of the metabolites observed in the rat metabolism study, it is unlikely that any of the identified metabolites in plants will be significantly more toxic than the parent.

Rotational crops: Trifluoroacetic acid (TFA) is the major metabolite found in rotational crops. Trifluoroacetic acid is also a potential common metabolite of other pesticides as well as a degradation product of chlorofluorocarbons (refrigerants). Environmental Fate and Effects Division (EFED) review also indicates that trifluoroacetic acid can be expected to be stable in the environment and to accumulate in bodies of water, including lakes and reservoirs. A limited literature search revealed no information that would indicate TFA toxicity exceeding the parent compound. However, the confined rotational crop study suggests the potential for significant exposure to TFA and on this basis additional information is needed before a decision on the need for rotational crop tolerances can be made. The MARC recommends that a limited rotational crop field trial study (with analysis for TFA) be submitted, along with any information available to the registrant from the literature, or other sources, concerning the toxicity of TFA.

Livestock: MARC concurs with the Agency's previous decision on no "reasonable" expectation of finite benfluralin residue (or benfluralin metabolites) in meat, milk, poultry, or eggs [Category 3, 40 CFR §180.6(a)].

Water: Environmental fate data indicate that benfluralin (parent) is immobile in soil. The two major routes of degradation in the environment are aqueous photolysis and soil photolysis, with half-lives of 9.9 hours and 12.5 days, respectively. The major photodegradates (>10% applied dose) are LY-48800(B35), LY-67255, LY-50030, LY-274766, LY-65138, LY-51783 (B34). The MARC considers these degradates to have similar toxicity to the parent based on the structural similarity to the parent. In addition, based on structure-activity analysis (EPIWIN v. 3.10), the degradates are all expected to be more mobile in soil (lower Kow), and more soluble in water than parent benfluralin. Thus, the degradates have a greater tendency to remain in water than the parent. Therefore, the MARC concludes that LY-48800(B35), LY-67255, LY-50030, LY-274766, LY-65138, LY-51783 (B34) are residues of concern in regard to drinking water. Degradate B12 was found at a high level of 0.133 ppm in an aerobic soil study, and fate data indicate that B12 is more mobile than parent benfluralin, and has a higher potential to leach to ground water than parent. Therefore, the MARC recommends that B12 be included in drinking water assessment.

Degradates B36 and B37 were found at 43% and 24% of the applied doses in anaerobic aquatic studies, and 0.254 ppm and 0.062 ppm in anaerobic soil studies. MARC concluded that these two degradates are the reduction form of the parent and that anaerobic soil/aquatic metabolism are not major routes of degradation in the environment. Therefore, it is not likely that these two degradates will reach drinking water in significant amounts, and can be excluded from risk assessment.

The registrant did not analyze for TFA in any of the laboratory or field environmental fate studies. However, based on the material balance in these studies, the concentration of TFA in surface water and ground water is not expected to contribute significantly over and above the estimated concentration of benfluralin (parent) and the other degradates recommended for aggregate risk assessment.

In summary, MARC recommends that for drinking water risk assessment, the residues of concern are parent plus LY-48800(B35), LY-67255, LY-50030, LY-274766, LY-65138, LY-51783 (B34), and B12.

cc: W. Eckel/ERBII/EFED(7507C)